K051625

510(k) SUMMARY

JUL 14 2005

Applicant:

Mölnlycke Health Care
826 Newtown Yardley Rd.
Newtown, PA 18940

Contact Person:

John Clay
Regulatory Affairs Officer

Tel.: 267-685-2078
Fax: 267-685-2010

Device Name:

Proprietary Name:	Barrier® Surgical Drapes
Common/Usual Name:	Surgical Drapes
Device Classification:	Class II – 21 CFR 878.4370 (KKX)

Substantial Equivalence:

For the purpose of Section 510(k) of the Federal Food, Drug and Cosmetic Act, Mölnlycke Health Care considers the BARRIER® Surgical Drape are substantially equivalent in composition, function and intended use to the previously marketed BARRIER® Surgical Drapes. The original BARRIER® Brand surgical drapes were pre-amendment devices manufactured by Johnson and Johnson Medical.

The first premarket notifications (K760807, K760902, K760933, K760937) were submitted in 1976 to cover the products already on the market. In 1978, additional submissions (K780282, K780839A, K780840A, K780841A, K780842A, K780843A, K780844A, K780856A) were made for modifications to the fabric in various surgical drape configurations to the Fabric 450® non-woven fabric used in the pre-amendment surgical gowns. Since 1978, several modifications and additions to the drape families have been made to the Barrier® drapes and packs, which have been cleared through multiple 510(k) submissions.

Intended Use:

BARRIER® surgical drapes are intended for single use to be used as a protective patient covering, such as to isolate a site on a surgical incision from microbial and other contamination.

Description: The BARRIER® Surgical Drapes have been designed with an assortment of fabrics, films and other materials and have been on the market for a number of years, cleared under multiple 510(k) notifications. BARRIER® surgical drapes, drape components and assorted surgical drape packs have been developed for a variety of surgical procedures including: Angiography, Cardiovascular/Thoracic, ENT/Plastic Surgery, OB/Gynecology, Laparascopic, Laparotomy, Orthopaedic, Urology, Cranial, Nephroscopy, Pediatric and other general surgical procedures. BARRIER® Surgical Drapes have been designed with materials, which provide increased protection to help prevent possible exposure to bloodborne pathogens and other potentially infectious materials.

Summary of Testing: BARRIER® Surgical Drapes have been evaluated using the ANSI/AAMI PB-70:2003 Standard. ***(Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities)***

The Barrier® Surgical Drapes are categorized into the following product groups: Patient Drapes, Equipment Drapes and Drape Components. All Barrier Drapes are categorized into ANSI/AAMI Level 2 or Level 4 based on material selection and construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

Mr. John Clay
Regulatory Affairs Officer
Molnlycke Health Care, Incorporated
826 Newton-Yardley Road
Newton, Pennsylvania 18940

Re: K051625
Trade/Device Name: BARRIER® Surgical Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: June 17, 2005
Received: June 21, 2005

Dear Mr. Clay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 051625

Device Name: BARRIER® Surgical Drapes

Indications for Use:

BARRIER® surgical drapes are intended for single use to be used as a protective patient covering, such as to isolate a site on a surgical incision from microbial and other contamination.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Murphy MD 7/7/05

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K051625